

### **III. REMARKS**

#### **Preliminary Remarks**

Claims 43-46 are currently withdrawn. Upon entry of the amendment, claims 22, 26-34 and 36-42 will be pending in this application.

**The applicant does not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserves the right to pursue such subject matter in continuing and/or divisional applications.**

Reconsideration and allowance of the present application based on the above-described amendments and the following remarks are respectfully requested.

#### **Claim for Priority**

Attached as Appendix A to this response is a copy of the first filing receipt issued by the United States Patent & Trademark Office (“USPTO”) in the instant case. The present application is identified as a continuation of parent U.S. Patent Application 09/053,152 filed April 1, 1998 and the application claims priority benefit of parent U.S. Patent Application 09/053,152 filed April 1, 1998, and of U.S. Patent Application 08/786,937 filed January 22, 1997, and of U.S. Provisional Application 60/011,282 filed February 7, 1996. Recognition of the applicants’ claim for priority benefit of parent U.S. Patent Application 09/053,152 filed April 1, 1998 is respectfully requested.

In response to the examiner’s assertion that the claim for priority was allegedly not perfected within the time periods set forth in 37 C.F.R. § 1.78(a), or that it was not requested in a grantable petition under 37 C.F.R. § 1.78(a), applicant respectfully submits the following.

As cited by the examiner, the Manual for Patent Examination and Procedure (“M.P.E.P.”) § 201.11 sets forth the requirements and procedures to be followed by examiners and applicants where a claim to a prior filed application under 35 U.S.C. §§ 119-120 is concerned. Specifically, both the official action and M.P.E.P. § 201.11 state that if reference to the prior application was previously submitted within the time periods set forth in 37 C.F.R. § 1.78(a), but not in the first

sentence of the specification or an application data sheet, and the USPTO recognizes the claim to priority by including it on the first filing receipt, the petition under 37 C.F.R. § 1.78(a) is not required. *See*, official action at page 8, item 8, *and*, M.P.E.P. § 201.11. Further, applicant is required to submit the amendment to the first sentence of the specification or an application data sheet to comply with 37 C.F.R. § 1.78(a).

As indicated in the amendment filed February 28, 2007, the claim to priority was included in the Request for Filing at page 1, lines 7-14, and in section 9, on page 2, which according to applicants records and the USPTO Patent Application Information Retrieval (“PAIR”) system, was filed September 15, 2003. The claim to priority, therefore, was made within the time limits set forth in 37 C.F.R. § 1.78(a). Further, applicant complied with the requirement to reference the priority claim in the first sentence of the specification or an application data sheet by filing an amendment on September 27, 2005 and an application data sheet on February 28, 2007. Moreover, the USPTO has recognized the claim to priority by issuing a filing receipt, June 22, 2007. A review of applicants’ file and the PAIR system indicates that this is the first filing receipt issued by the USPTO in the instant application. Applicant, therefore, respectfully submits that a proper priority claim under 37 C.F.R. § 1.78(a) is now perfected, there is no requirement to file a petition for such priority claim, and the examiner is requested to recognize the priority claim set forth in the USPTO filing receipt.

#### Amendment to the Specification

The first paragraph on page 1, which was previously amended by the amendment filed on September 27, 2005, and by the amendment filed on February 28, 2007 is further amended to identify the current status of parent U.S. Patent Appl. No. 08/786,937, filed January 22, 1997. The amendment filed on February 28, 2007 erroneously identified the status of U.S. Patent Appl. No. 08/786,937, filed January 22, 1997, as abandoned. U.S. Patent Appl. No. 08/786,937, filed January 22, 1997 is currently pending.

**Withdrawn claims 43-46**

The examiner asserts that claims 43-46 are directed to an invention that is allegedly independent or distinct from the originally claimed invention and that by presentation and receiving an official action on the merits, applicant has elected an invention directed to a method of treating infertility disorders by administering an LHRH-antagonist and inducing follicle growth by hMG or FSH in combination with clomiphene. Further, the examiner asserts that claims 43-44 are directed to a method of controlled ovarian stimulation, claims 45-46 are directed to a method of treating fertility disorders by administering an LHRH-antagonist and inducing follicle growth by hMG or FSH in combination with clomiphene and performing assisted reproduction techniques following induction of ovulation, and that these methods are independent and distinct from the methods set forth in currently pending claims 22, 26-34 and 36-42. Applicant respectfully disagrees.

The burden is on the examiner to provide an example to support the determination that the inventions are distinct, but the example does not have to be documented. M.P.E.P. § 806.05(j). If, however, the applicant either proves or provides convincing evidence that the example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement. *Id.* Related process inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and, the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. *See* MPEP § 802.01.

A method of controlled ovarian stimulation is one of several methods for treating infertility disorders in females. For example, the specification as filed details that the existing methods of treating fertility disorders include ovarian hyperstimulation and problems associated with this include premature LH surges causing rupture of immature follicles and life-threatening ovarian hyperstimulation syndromes. Specification at page 1, line 17, through page 2, line 9. Further, the specification describes the result of a phase II clinical trial for infertility patients undergoing COS/ART (controlled ovarian stimulation/assisted reproductive technologies). Specification at page 6-7 and Table I. The doses of cetrorelix and methods encompassed by claims 22, 26-34 and 36-42 are included in these portions of the specification. Claims 43-44,

therefore, overlap in scope with, are obvious variants of, and have a similar function and effect as claims 22, 26-34 and 36-42. Thus, claims 43-44 are not distinct from claims 22, 26-34 and 36-42.

Additionally, claims 45-46, in relation to pending claims 22, 26-32 and 36-42 include the additional step of performing assisted reproduction techniques following induction of ovulation. Throughout the specification, reference is made to the use of LHRH antagonists to treat male and female fertility disorders, that many assisted reproduction techniques are now available and include techniques to induce multiple and synchronous follicular growth. *See, e.g.*, specification at page 1, line 12-21. Claims 45-46, therefore, overlap in scope with, are obvious variants of, have a similar function and effect as, and can be used with the method of claims 22, 26-34 and 36-42. Thus, claims 45-46 are not distinct from claims 22, 26-34 and 36-42. Accordingly, applicant respectfully requests the examiner withdraw the assertion that claims 43-46 are directed to a non-elected invention, or set forth the reasons required by M.P.E.P. § 806.05(j), so that applicant can file divisional applications claiming the subject matter of claims 43-46.

### **Patentability Remarks**

#### ***35 U.S.C. §102(a)***

Claims 22, 28-32, 36, and 39-42 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Hwang *et al.* (2003).

As indicated above, the present application is recognized by the USPTO as claiming priority benefit of the April 1, 1998, filing date of U.S. Patent Application No. 09/053,152, of which the present application is a continuation application. Accordingly, the Hwang et al. (2003) publication is not available as prior art. Withdrawal of the rejection of claims 22, 28-32, 36, and 39-42 under 35 U.S.C. § 102(a) as allegedly being anticipated by Hwang et al. (2003) is respectfully requested.

#### ***35 U.S.C. §102(b)***

Claims 22, 26, 28 and 39-42 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Craft *et al.* (1999).

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Claims 22, 27, 28, 36, 37 and 39-42 are rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Engel *et al.* (2002).

Claims 22, 33-38 and 39 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Engel *et al.* (WO 99/55357, published November 4, 1999).

With regard to the foregoing three grounds for rejection under 35 U.S.C. § 102(b), as indicated above, the present application is recognized by the USPTO as claiming priority benefit of the April 1, 1998, filing date of U.S. Patent Application No. 09/053,152, of which the present application is a continuation application. Accordingly, the Craft *et al.* (1999), Engel *et al.* (2002), and Engel *et al.* (WO 99/55357, 1999) publications are not available as prior art against the claims of the present application. Withdrawal of the rejection under 35 U.S.C. § 102(b) of claims 22, 26, 28 and 39-42 as allegedly being anticipated by Craft *et al.* (1999), of claims 22, 27-28, 36-37 and 39-42 as allegedly being anticipated by Engel *et al.* (2002), and of claims 22, 33-38 and 39 as allegedly being anticipated by Engel *et al.* (WO 99/55357, 1999), is therefore respectfully requested.

**IV. CONCLUSION**

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If the examiner identifies any points that he feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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